

Section 5**510(k) Summary****1. SUBMITTER INFORMATION**

Establishment / Sponsor Name: Invivo Corporation
Establishment / Sponsor Address: 12151 Research Parkway
Orlando, FL 32826 USA

Manufacturer Name: Philips Medical Systems
Manufacturer Address: 3000 Minuteman Road
Andover, MA 01810 USA

Company Phone: (407) 455-6166

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Person to contact
regarding questions: Rusty Kelly
Sr. Quality & Regulatory Manager, Invivo Corporation
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Establishment
Registration Number: 1051786 (Sponsor)
1218950 (Manufacturer)

Date Summary Prepared: July 15, 2013

AUG 30 2013

2. MODIFIED DEVICE IDENTIFICATION

Trade / Proprietary Name: Expression MRI Patient Monitoring System (Model 865214)

Common name: MRI Patient Monitoring System

Classification name: Cardiac monitor (including cardiometer and rate alarm)
(21 CFR 870.2300, Product Code MWI)

3. IDENTIFICATION OF LEGALLY MARKETED CLEARED DEVICE

The MRI Patient Monitoring System (Model 865214) is substantially equivalent to the following cleared device:

Cleared Device	Manufacturer	510(k) No.	Clearance Date
MRI Patient Monitoring System (Model 865214)	Invivo Corporation	K124061	Feb 22, 2013

4. MODIFIED DEVICE DESCRIPTION

The modified device, MRI Patient Monitoring System (Model 865214), is substantially equivalent to the cleared device. Invivo began marketing the cleared device, MRI Patient Monitoring System (Model 865214) in 2009. In 2012 Invivo identified the opportunity to reduce healthcare costs by replacing the temperature option which was an Ethylene Oxide (EO) sterilized, single-use temperature sensor with a reusable temperature sensor that utilizes single-use, gamma irradiated sterilized jackets (sheath) and submitted a special 510(k) which received clearance to market on Feb 22, 2013.

Since February 22, 2013 we have determined that the production process used to manufacture the temperature sensor is not able to meet the necessary production yield. Therefore, the production process has been modified to improve yield. The modifications to the production process have indirectly affected the measurement accuracy of the reusable temperature sensor within the MRI environment as described below.

The modified device, MRI Patient Monitoring System (Model 865214) and the cleared device, also identified as MRI Patient Monitoring System (Model 865214) which received clearance to market under 510(k) K124061 on February, 22 2013, are identical with respect to indications for use, intended use, fundamental scientific technology, software architecture, and design. Both devices are multi-parameter patient monitors intended for use by healthcare professionals to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. Both devices provide patient monitoring data for ECG, SpO2, respiration, non-invasive blood pressure (NIBP), invasive blood pressure (IBP), temperature, oxygen (O2), end-tidal carbon dioxide (EtCO2), and anesthetic agents.

The modifications to the cleared device are only in regards to the temperature parameter, specifically the reusable temperature sensor. The primary differences between the MRI Patient Monitoring System (Model 865214) and the cleared device are listed below:

- The accuracy of the cleared device is $\pm 0.5^{\circ}\text{C}$ ($\pm 0.9^{\circ}\text{F}$), whereas the accuracy of the modified device is $\pm 0.5^{\circ}\text{C}$ ($\pm 0.9^{\circ}\text{F}$) except inside the MR system magnet bore where the magnetic field creates up to a -0.5°C shift (-1.0°C to 0.0°C , -1.8°F to 0.0°F)
- Device labeling has been updated to reflect the modified measurement accuracy accordingly.

The differences between the modified device, MRI Patient Monitoring System (Model 865214), and the cleared device are explained in greater detail in Section 12, the Substantial Equivalence Discussion, which includes a comparison table. No modifications have been made to the software or design of the patient monitor itself or the single-use jacket (sheath) used with the temperature sensor including its sterilization method.

5. INTENDED USE

The intended use of the modified device, as described in its labeling, has not changed from that of the cleared device as a result of the modification.

The MRI Patient Monitoring System (Model 865214) is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The MRI Patient Monitoring System (Model 865214) is intended for use by healthcare professionals.

6. FUNDAMENTAL SCIENTIFIC TECHNOLOGY SUMMARY

The fundamental scientific technology employed in the operation of the MRI Patient Monitoring System (Model 865214) as modified, has not changed from that of the cleared device as a result of the modification. A detailed explanation of the fundamental scientific technology is provided in Section 11 of this submission.

7. NON-CLINICAL PERFORMANCE DATA SUMMARY

The performance data referenced in this submission establishes substantial equivalence of the modified device, the MRI Patient Monitoring System (Model 865214), to the cleared device which received market clearance on February 22nd, 2013 under 510(k) K124061.

The modified device was evaluated to the following safety and performance tests:

- I. Voluntary consensus standards
- II. Verification and validation of performance specifications
- III. Verification and validation of MR conditions of use

In all testing, the device was verified using a worst-case environment.

I. Voluntary Consensus Standards

The MRI Patient Monitoring System (Model 865214) was evaluated to the following voluntary standards, where applicable to the modifications, per FDA Guidance titled "*Use of Standards in Substantial Equivalence Determination*". Standards are listed in Section 1 of the CDRH Premarket Review Submission Cover Sheet included in this submission. A declaration of conformity to the recognized consensus standards is included in Section 9 of this submission with a Standards Summary Report Table noting deviations and adaptations. Additionally, the Standards Data Reports for 510(k) for each voluntary standard (based on Form FDA 3654 (09/07)) is included in Section 21 of this submission.

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests
- IEC 60601-1-6, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Usability
- IEC 60601-2-49, Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ASTM E1112-00, Standard specification for electronic thermometer for intermittent determination of patient temperature
- ISO 14971, Medical devices – Application of risk management to medical devices
- ASTM F2503–08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
- ASTM F2052-06, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- BS EN 12470-4, Clinical thermometers. Performance of electrical thermometers for continuous measurement
- ISO 10993-1, Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process
- ISO 10993-5, Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity

The results of the testing performed in accordance with the Voluntary Consensus Standards listed above demonstrate that the modified device is as safe and effective as and substantially equivalent to the cleared device. Evidence of this is documented in Section 18 of this submission.

II. Verification and Validation of Performance Specifications

Temperature measurement parameters of the MRI Patient Monitoring System (Model 865214) were verified according to the performance specifications defined by Invivo Corporation according to national standards, international standards, market needs, risk management, and intended use.

Results of the complete verification and validation indicate that the modified device operates as intended within the performance specifications. Clinical data was not required to substantiate claims of safety and effectiveness. Performance data is available throughout Section 18 and the risk assessment is available in Section 22 to support our claims of safety and effectiveness and determination of substantial equivalence. Based upon the design validation and risk assessment,

specifications and labeling modifications do not raise new concerns regarding safety or effectiveness of the modified device.

Verification and validation of the other vital sign parameters—ECG, SpO₂, NIBP, IBP, end-tidal CO₂ (ETCO₂), oxygen (O₂), and anesthetic agents—are not required because the device modifications pertain only to the temperature parameter, specifically the reusable temperature sensor.

III. Verification and Validation of MRI Conditions of Use

The MRI conditions of use of the modified device are defined by Invivo Corporation according to national standards, international standards, intended use, risk management, and market needs. The modified device's reusable temperature sensor was evaluated for magnetically induced displacement force, proton emissions, image artifact, and RF heating. Details are provided in Section 18.

Test results demonstrate that the MRI Patient Monitoring System (Model 865214) meets the MRI conditions of use as defined in the modified device labeling.

8. **CONCLUSION OF SUBSTANTIAL EQUIVALENCE**

The modified device, described in this submission is substantially equivalent to the cleared device. This conclusion is based on the guidance provided in the FDA Guidance Documents:

- Deciding When to Submit a 510(k) for a Change to an Existing Device (Issued January 10, 1997)
- 510(k) "Substantial Equivalence" Decision Making Process (last updated April 25, 2009)
- Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers (issued March 1993)

The modifications do not affect the indications for use. Clinical data was not necessary to establish safety and effectiveness for the purpose of substantial equivalence of the cleared device, and design validation did not raise new questions regarding the safety and effectiveness of the modified device. Specifications and labeling modifications do not raise new concerns regarding safety or effectiveness. Performance data is available throughout Section 18 and the risk assessment is available in Section 22 to support our claims of safety and effectiveness and determination of substantial equivalence.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 30, 2013

Invivo Corporation
Rusty Kelly
12151 Research Pkwy
Orlando, FL 32826 US

Re: K132359
Trade/Device Name: MRI Patient Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Monitor, Physiological, Patient
(Without Arrhythmia Detection or Alarms)
Regulatory Class: II
Product Code: MWI
Dated: July 15, 2013
Received: August 2, 2013

Dear Rusty Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Owen P. Baris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: MRI Patient Monitoring System (Model 865214)

Indications for Use: The MRI Patient Monitoring System (Model 865214) is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner.

The MRI Patient Monitoring System (Model 865214) is intended for use by healthcare professionals.

Prescription Use: X AND/OR Over-the Counter Use: _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Owen R. Faris -S
Date: 2013.08.30
14:53:29 -04'00'



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